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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,903	11/21/2003	Ulrike Schmid	059490-5025	7366

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EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/717,903	<b>Applicant(s)</b> SCHMID ET AL.	
	<b>Examiner</b> Susan D. Coe	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/12/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 1-14 are currently pending.

#### *Election/Restrictions*

2. Applicant's election of Group I, claims 1-13 in the reply filed on February 15, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claim 14 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 15, 2005.
4. Claims 1-13 are examined on the merits.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of diarrhea, does not reasonably provide enablement for prevention of diarrhea. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Art Unit: 1654

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to a method of preventing diarrhea. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition in each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed method is able to prevent diarrhea for all potential causes of diarrhea. For example, known causes of diarrhea include bacterial infection, viral infection, food intolerance, parasites, reactions of medicines, and functional bowel disorders (see <http://digestive.niddk.nih.gov/ddisease/pubs/diarrhea/> - page 2). Applicant's specification only shows a link between the claimed composition and treating diarrhea caused by bacterial infection. Applicant does not show that the composition is able to prevent diarrhea. Thus, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually function as claimed. Therefore, the claims are not considered enabled for the prevention of diarrhea.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1654

6. Claim 1 is rendered indefinite by the use of parentheses. The use of parentheses is considered indefinite because it is not clear if the enclosed limitation is a required limitation in the claim.

7. Claim 2 is indefinite because it is not clear what age ranges are encompassed by “babies.”

8. Claims 3 and 12 are indefinite because there is a lack of antecedent basis for “the natural.” In addition, in claim 3, it is unclear what is meant by “the natural composition.” Does this mean that the sterols or pentacyclotriterpenes are present in the same form and amounts in an extract form?

9. Claim 5 is indefinite because there is a lack of antecedent basis for “the free hydroxysterols.” In addition, it is unclear how the use of “free” is meant in context of the hydroxysterols.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,149,961.

Applicant’s claims are drawn to a method for making a food product containing carbohydrates, proteins, and phytosterols and/or pentacyclotriterpenes derived from Shea oil. The food product is intended for use as an anti-diarrheal or anti-scouring composition.

Art Unit: 1654

US '961 teaches a method of making food products using sterols derived from Shea nut. The Shea sterol extract specifically contains alpha-amyrin and other phytosterols (see column 3). The sterol extract can be used in foods in amounts from 0.1% to 95% (see column 5, first two full paragraphs). This sterol extract is specifically used in an example that contains 14% sterols in combination with carbohydrates and proteins (see Table 2).

The reference does not specifically teach that the food products containing the sterols has anti-diarrheal or anti-scouring properties. However, the reference teaches making a food product that is the same as the claimed method of making. Thus, the food product made according to the reference would inherently have the effects claimed if applicant's invention functions as claimed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1654

11. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/056879 in view of WO 02/055087.

Applicant's claims are drawn to a method of treating diarrhea using phytosterol and/or pentacyclotriterpenes derived from Shea oil. Specifically piglets are treated. Specific compounds used are alpha-amyrin, beta-amyrin, butyrospermol, and lupeol.

WO '879 teaches that diarrhea is significant causes of illness in neonatal and weanling piglets. The cause of this diarrhea is bacterial infection and is treating with antibiotics (see pages 11 and 12). Thus, the reference teaches treating diarrhea in piglets using antibiotics. However, the reference does not specifically teach using the claimed compounds to treat diarrhea.

WO '087 teaches triterpene compositions containing butyrospermol, lupeol, alpha-amyrin, and beta-amyrin (see page 13, first paragraph). These triterpene compositions can be used to treat bacterial infections (see page 16, first full paragraph). Thus, a person of ordinary skill in the art would reasonably expect that the antibacterial triterpene composition of WO '087 could be used to treat diarrhea as taught by WO '879. based on this reasonable expectation of success, an artisan of ordinary skill would be motivated to use butyrospermol, lupeol, alpha-amyrin, and beta-amyrin to treat diarrhea.

The references do not specifically teach using the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some

Art Unit: 1654

demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

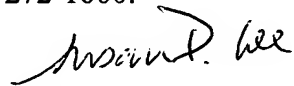
12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.



3-16-05

Susan D. Coe  
Primary Examiner  
Art Unit 1654